

to, or internal within, the body. In reference to claim 5, Magovern teaches that the energy transfers alters the airway in such a manner that the ability of the airway to narrow is reduced. See Magovern Col. 2, line 31-40.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Here, Magovern fails to describe an element required in claim 1. In particular, Magovern does not describe the step of transferring energy to an airway wall in a lung. Magovern instead describes supplying energy to a shape memory structure having an activated shape and a quiescent shape. In Magovern, the shape memory structure -- not lung tissue -- is responsive to the application of energy. Accordingly, Magovern fails to show all of the elements required in claim 1.

Based on the foregoing, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(e) as being anticipated by Magovern is respectfully requested.

Since claims 2-3, 5, 41, and 42 depend from claim 1 and consequently include each of the features and limitations of claim 1, these claims are also not anticipated by Magovern. Accordingly, reconsideration and withdrawal of the rejections of claims 2-3, 5, 41, and 42 are respectfully requested.

Rejections under 35 U.S.C. §102(b)

Claims 1-3, 5, 11, 12, 41, 42, and 45-49 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,505,728 to Ellman et al. (Ellman). The Office Action provides:

Ellman discloses an electrode for use in electrosurgical procedure to improve [] snoring and sleep apnea. Ellman teaches a procedure of reducing snoring or sleep apnea by electrosurgically stripping layers of tissue of the wide lateral [pharyngeal] walls and low arched soft palate on both sides of the uvula, said procedure being carried out via the oral cavity of the patient while sparing the uvula. Ellman's procedure alters the structure of the airway wall by decreasing the thickness of the airway wall, thus inherently

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treating the conditions of the lungs by decreasing airway resistance to airflow. See Fig. 4 of Ellman.

Applicants respectfully disagree. Like Magovern, Ellman also fails to disclose transferring energy to an airway wall in the lungs. Ellman merely describes electrically shaving or stripping layers of tissue within the oral cavity and not the within the lungs. Moreover, Ellman says nothing about treating the lungs. Accordingly, Ellman does not anticipate claims 1 and 46.

Claims 2-3, 5, 11, 12, 41, 42, 45 and 47-49 depend from claim 1 or claim 46. Consequently, claims 2-3, 5, 11, 12, 41, 42, 45 and 47-49, which include each of the features and limitations of claims 1 or 46, are not anticipated by Ellman.

Based on the foregoing, withdrawal of the rejections of claims 1-3, 5, 11, 12, 41, 42, and 45-49 as being anticipated by Ellman is respectfully requested.

Rejections under 35 U.S.C. §103(a)

A. Claim 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Magovern in view of Wiggs et al. ("On the mechanism of mucosal folding in normal asthmatic airways," American Physiological Society, 0161-7569/97) (hereafter referred to as "Wiggs").

The Office Action provides:

Magovern has been described above. However, although Magovern's energy transfers alters the airway in such a manner that the ability of the airway to narrow is reduced, he does not teach a method of treating asthma by preventing the contraction of the airways. Wiggs simulates the effect of smooth muscle shortening and also describes its effect on airway walls, as seen in asthma patients. In a detailed discussion, Wiggs teaches that the narrowing of the airways may cause airflow obstructions, thereby making it difficult for asthma sufferers to breath. Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify Magovern's invention in view of Wiggs and prevent the narrowing of the airways in order to relief asthma patients from breathing difficulties.

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Applicants respectfully disagree. The Office Action does not set forth a prima facie case of obviousness.

According to MPEP § 2142, “[t]he Examiner bears the initial burden of factually supporting a prima facie case of obviousness.” To make a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Third, the reference(s) must teach or suggest all the claim limitations. *Id.* at § 2143.

With respect to claim 4, a prima facie case of obviousness has not been established. First, there is no motivation to modify the cited references as proposed in the Office Action because neither Magovern nor Wiggs discloses or suggests the application of energy to an airway wall in a lung.

Second, there is no indication of how successful the shape memory alloy structure in Magovern would operate in a lung. Wiggs likewise provides no indication of success.

Third, no combination of Magovern and Wiggs discloses or suggests each of the elements required in claim 4. Specifically, no combination of Magovern and Wiggs show the step of transferring energy to an airway wall in the lungs. As indicated above, Magovern does not show transferring energy to an airway wall in the lungs. Wiggs likewise fails to suggest transferring energy to an airway wall in the lungs.

Accordingly, the Office Action fails to establish a prima facie case of obviousness. Reconsideration and withdrawal of the rejection of claim 4 based on obviousness is therefore requested.

B. Claims 6, 13, and 50-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ellman in view of U.S. Patent No. 5,624,439 to Edwards et al. (Edwards) and U.S. Patent No. 6,053,172 to Hovda et al. (Hovda). The Office Action provides:

Ellman, described above, does not teach a method for treating airway by moving energy transfer device along the airway. Edwards discloses a method and apparatus for treatment of airway obstructions comprising a first arm including a proximal end and a distal end, the first arm distal end is inserted into the throat and positioned adjacent to a back surface of the tongue. Edwards further teaches that a plurality of RF electrodes are positioned in the first arm wherein said electrodes are advanced into the back of the tongue in order to ablate a selected area of the back of said tongue. Hovda discloses a system and method for selectively applying electrical energy to a target location within the head and neck of a patient's body, particularly including tissue in the ear, nose, and throat. In addition, Hovda teaches that a high frequency electrical energy, applied to one or more electrode terminals, is used to modify the tissue structure. See Fig. 14 of Hovda. Hovda also teaches that his invention is particularly useful for removing occlusive media within a small body passages.

Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify Ellman's procedure in view of Edwards and in view of Hovda and move the energy transfers device along the airway in order to reduce tissue inflammation, and alter the function of the airway wall by altering the resting tone of the airway wall.

Applicants respectfully disagree. Just as discussed above with respect to claim 4, the Office Action does not set forth a prima facie case of obviousness for the rejections of claims 6, 13, and 50-54.

As indicated above, Ellman lacks a meaningful element of the claims. That is, Ellman fails to describe application of energy to the airway wall in the lungs. In contrast, Ellman describes electrically shaving or stripping layers of tissue within the oral cavity, not the lungs.

Neither Edwards or Hovda cure this deficiency. Consequently, no combination of the cited references show or suggest all the elements required in claims 6, 13, and 50-54, much less a reasonable expectation of success.

Accordingly, reconsideration and withdrawal of the rejections of claims 6, 13, and 50-54 is respectfully requested.

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CONCLUSION

Applicants have, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 435712000920. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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